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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,238	10/12/2005	Marco Frentsch	GULDE-0057	7138

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
01/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,238	FRENTSCH ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1-3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-12 are pending.

2. It is noted that claims 1-3 are directed to the "use" of a compound. "Use" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki , 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner,255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

Therefore, claims 1-3 have been withdrawn from consideration as being drawn to non-statutory subject matter.

If these claims are amended to recite statutory subject matter, the amended claims may be rejoined with the appropriate invention Group as set forth below.

3. While an election of species has been set forth herein, it is noted that the claims Appear indefinite under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as they do not recite clear and definitive method steps and appear to be incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Applicant is invited to review the claims carefully and consider amending the claims to recite positive steps and ingredients to accomplish the claimed methods.

For example, the repeated recitation of "and/or" is confusing.

For example, applicant is invited to avoid reciting "used" and recite clear positive steps and ingredients to accomplish the claimed methods.

For example, the nature and parameters with respect to the recitation of "characterized" is that the nature or parameters of the claimed "characterization" is not defined by the claims and the specification does not provide a standard for ascertaining the requisite degree or direction and, in turn, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention or the parameters by which to determine said metes and bounds.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

4. While applicant has provided an Information Disclosure Statement based upon the International Search Report,
applicant has not provided the reference cited upon the IDS.

Applicant should provide the references cited on the IDS to complete the instant file application.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

(A) This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the methods are directed towards:
(1) methods for detection,
(2) methods for isolation,
(3) methods for detection and isolation,
(4) methods for detection and use in therapies,
(5) methods for isolation and use in therapies, OR
(6) methods for detection, isolation and use in therapies.

(B) In addition to electing a species from (A) above,
This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the methods rely upon a CD40/CD154 system inhibitor selected from those recited in claim 4-7 and those disclosed on pages 13-15 of the instant specification.

Applicant is required to elect a particular species of a CD40/CD1254 system inhibitor (e.g., anti-CD40 antibody, brefeldin A, etc.).

(C) In addition to electing a species from (A) and (B) above,
This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the detection of CD154 is
(1) intracellular or
(2) extracellular.

(D) In addition to electing a species from (A), (B) and (C) above,
This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the detection of CD154 is in/on
(1) fixed cells or
(2) vital cells.

(E) In addition to electing a species from (A), (B), (C) and (D) above, if appropriate, This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the use in cellular therapy is selected form the infectious, allergic, inflammatory, malignant and autoimmmune diseases recited in claim 12 or disclosed on page 16 of the instant specification.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

It is noted that Assenmacher et al. (WO 99/58977) (1449; #002) teach detecting and selecting / isolating antigen-specific T cells based upon CD154-/ CD40L-specific antibodies and employing said enriched antigen-specific T cells (see entire document, including Effector Cell Populations on pages 26-29, Cell Analysis on pages 36-39, Diagnostic Methods for Detecting Antigen-Specific T Cells on pages 39—40 and Methods of Treatment Using Enriched Antigen-Specific T Cells on pages 40-42).

The invention as well as the species do not provide a contribution over the prior art in that the special technical feature of employing CD154-specific/ CD40L-specific reagents/inhibitors, such as CD40L-specific antibodies have been employed in the detection and isolation of antigen-specific T cells, including their use for diagnostics and therapy.

Further, the species listed above in (A) – (E) do not relate to a single general inventive concept in that the species lack the same or corresponding special technical features for the following reasons.

For example, the methods rely upon different ingredients, steps and endpoints.

In turn, the ingredients for the methods, including the CD40/CD154 system inhibitors, differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered patentable distinct. Further, these molecules do not share a substantial structural feature essential to a common utility do not have common structure to a common utility.

Further, the diseases differ in etiologies and therapeutic endpoints.

Thus the technical feature of employing CD40L-specific reagents in detecting, isolating and using antigen-specific T cells was not special and the species are not so linked under PCT Rule 13.2.

Additionally, the claimed methods rely upon different ingredients, process steps and endpoint which are not coextensive and which do not share the same technical feature.

7. Applicant is required, in reply to this Office Action, to elect a single species as it reads on each of (A)- (E) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

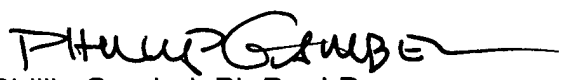
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841 until January 3, 2007.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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